PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P566.PC.31	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/01725	International filing date *(day/month/year)* 28.04.2003	Priority date *(day/month/year)* 30.04.2002
International Patent Classification (IPC) or both national classification and IPC A61B17/16		
Applicant PRECIMED S.A. et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.11.2003	30.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Nice, P Telephone No. +31 70 340-2354

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/01725

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-6 as originally filed

Claims, Numbers

1-16 received on 14.06.2004 with letter of 14.06.2004

Drawings, Sheets

1/12-12/12 as published

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item IV
Lack of unity of invention

The International Examining Authority agrees with the objection of lack of unity raised by the International searching Authority. The following inventions have been identified:

1. Claims: 1-5, and claims 10-16 when dependent on claims 1-5

Surgical reamer with housing members separable along a plane parallel to a longitudinal axis

2. Claims: 6-9, and claims 10-16 when dependent on claims 6-9

Surgical reamer with handle adjustably lockable in angular positions

The present application lacks unity within the meaning of Rule 13 of the PCT for the following reasons :

From DE2547969 ("D1") a surgical reamer spindle is known (the numerals in parentheses referring to this document) having at one end a reamer holder (3), including a housing enclosing a drive train (2) and comprised of at least two members (7,8,9) of which a pair (8,9) are matching, the ends being retained in a drive-train-enclosing relationship by a capture mechanism (10,11) and the housings being separable from one another. There is a handle (12) with a lockable adjustment mechanism including a ring (14) and a sleeve (6) to which the handle is connected further with an elastic device (17) so as to bias the sleeve and the handle and facilitate disassembly.

Over this prior art the special technical features (in the meaning of PCT Rule 13.2) claimed in the application are :

1. Claim 1, and claims dependent thereon:

The housings are separable along a plane parallel to the axis, and the drive train capture mechanism includes an elastic device.

2. Claim 6, and claims dependent thereon:

The handle can be locked in different angular positions, and the handle adjustment mechanism elastic device is disposed between the sleeve and the ring.

The special technical features solve different problems, namely :

1. The drive train and housing of the prior art device cannot be disassembled and hence cleaned unless both are straight. A straight reamer however does not allow the optimum incision to be used. If the housing can be disassembled parallel to the axis the drive train and housing can have bends.

2. The handle of the prior art device can be moved longitudinally but not angularly, preventing left- and right-handed surgeons surgeon getting the ideal grip with regard to comfort and keeping the handle out of the way. Angular adjustability of the handle avoids this problem.

The special technical features of the two groups of claims are neither the same nor, since the problems which they solve are different, are they corresponding. Therefore the requirement of unity of invention (PCT Rule 3.1) is not fulfilled.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D2: DE-A-3828478
D3: US-A-2093682

2 Document D2, which is considered to represent the most relevant state of the art for claim 1, discloses (the numerals in parentheses referring to this document):

A surgical reamer spindle which is easily disassembled for cleaning, the spindle being elongated, having first and second ends and a central housing (183), the housing substantially enclosing a drive train (184) and comprised of at least two housing members (183a), wherein at least one of the first and second ends is

retained in a drive-train-enclosing relationship by a capture mechanism (189) which may comprise a locking ring (see D2 column 18 line 13-16), the at least two housing members [erroneously called housings] being separable from one another to permit cleaning and/or changing of the housing members for other housing members of a different form in order to suit different surgical protocols.
(See D2, figures 39 and 41; column 16, line 50 - 19; column 17, line 48-56; and column 17, line 67 - column 18, line 8.)

The subject matter of claim 1 differs from this prior art in that the locking ring is biased by an elastic device, and separation of the housing members takes place along a plane parallel to the longitudinal axis of the housing. The subject matter of claim 1 is therefore novel (Article 33(2) PCT).

The problem to be solved by this present invention may be regarded as devising a more convenient why of dis-assembling a split-housing reamer spindle. It is not obvious for the skilled practitioner to solve this problem by elastically biasing the locking ring, as this requires major alterations to the remainder of the device. Hence an inventive step is present in the subject matter of claim 1 (Article 33(3) PCT).

3 Document D3, which is considered to represent the most relevant state of the art for claim 6, discloses (the references in parentheses referring to this document):

An elongated surgical reamer spindle having an adjustable handle (1,2) which is easily disassembleable for cleaning, the spindle having first and second ends and a central housing (4), the housing substantially enclosing a drive train (7,8,9), wherein a lockable adjustment mechanism adjustably locks the handle in angular positions about the spindle, the lockable adjustment mechanism comprising a locking ring (4a) and a locking sleeve (3) to which the adjustable handle is connected, wherein further an elastic device (30) is disposed between the locking sleeve (3) and the locking ring (4a) so as to bias the locking ring (4a) in a locking position and to bias the locking sleeve(3), and thus the handle (1,2), in a selected angularly locked position about the housing(4).
(See D3, page 1, left-hand column, lines 28-56, and figures 3 and 6.)

From this prior art the subject matter of claim 6 differs in that removal of the locking ring against the bias of the elastic device facilitates disassembly of the

spindle for cleaning. The subject matter of claim 6 is therefore novel (Article 33(2) PCT).

The problem to be solved by this present invention may be regarded as devising a more convenient why of dis-assembling a reamer spindle with an adjustable handle. It is not obvious for the skilled practitioner to solve this problem by using the handle locking ring to disassemble the spindle, as this requires major alterations to the remainder of the device. Hence an inventive step is present in the subject matter of claim 6 (Article 33(3) PCT).

4 Claims 2-5 are dependent on claim 1, claims 7-9 are dependent on claim 6, and claims 10-16 may be dependent on either claim 1 or claim 6, and as such they also meet the requirements of the PCT with respect to novelty and inventive step.

Replaced by ART 34 AMDT

What is claimed is:

1. A surgical reamer spindle (15, 115) which is easily disassembled for cleaning, the spindle being elongated, having first and second ends and a central housing (113, 213, 313, 314, 413, 414, 502), the housing substantially enclosing a drive train (207) and comprised of at least two housing members (113, 213, 313, 314, 413, 414), wherein at least one of the first and second ends is retained in a drive-train-enclosing relationship by a capture mechanism (455, 490, 486, 502) comprising a locking ring (455) and an elastic device (486), the locking ring biased in a locking position by the elastic device, the at least two housings being separable from one another approximately along a plane substantially parallel to a longitudinal axis (116) of the housing to permit cleaning and/or changing out of the housing members for other housing members of a different form in order to suit different surgical protocols.

2. The surgical reamer spindle of claim 1 wherein the capture mechanism (455, 490, 486, 502) further comprises a locking sleeve (482a) to which a repositionable handle (500) is attached, wherein the elastic device (486) is disposed between the locking sleeve and the locking ring so as to bias the locking ring in a locking position and to bias the locking sleeve, and thus attached repositionable handle, into a locked angular position about an axis (116) of the spindle, the locking ring aiding in holding the reamer spindle together, wherein removal of the locking ring against an elastic bias of the elastic means unfastens an end of the assembly in order to facilitate disassembly and/or cleaning.

3. The surgical reamer spindle of claim 2, wherein the locking sleeve (482a) has recesses (482c) for receiving pins (484) engaged in a shoulder (502c) fixed to the housing, the locking sleeve, and thus the adjustable handle (500), locking when the pins are received into the recesses, thereby locking the locking sleeve to the shoulder and thus to the housing.

4. The surgical reamer spindle of claim 2, wherein the locking ring (455) has at least one pin (411) affixed thereto, the at least one pin locking the locking ring in a locking position when the locking ring is biased into a bayonet recess (260, 492) by the elastic device (486).

Replaced by ART 34 AMDT

5. The reamer spindle of claim 1, wherein the drive train (207) is selected from a group of drive trains consisting of nickel titanium drive trains, ferrous metal drive trains, flexible round wound cable drive trains, flat wire wound cable drive trains, gear-driven shaft drive trains, and drive trains having shafts connected via universal joints.

6. An elongated surgical reamer spindle (315) having an adjustable handle (500) which is easily disassembleable for cleaning, the spindle having first and second ends and a central housing (113, 213, 313, 314, 413, 414, 502), the housing substantially enclosing a drive train (207), wherein an lockable adjustment mechanism (450) adjustably locks the handle in angular positions about the spindle, the lockable adjustment mechanism comprising a locking ring (455) and a locking sleeve (482a) to which the adjustable handle is connected, wherein further an elastic device (486) is disposed between the locking sleeve and the locking ring so as to bias the locking ring in a locking position and to bias the locking sleeve, and thus the handle, in a selected angularly locked position about the housing, wherein removal of the locking ring against the bias of the elastic device facilitates disassembly of the spindle for cleaning.

7. The surgical reamer spindle of claim 6, wherein the locking sleeve (482a) has recesses (482c) for receiving pins (484) engaged in a shoulder (502c) fixed to the housing, the locking sleeve, and thus the adjustable handle (500), locking when the pins are received into the recesses, thereby locking the locking sleeve to the shoulder and thus to the housing.

8. The surgical reamer spindle of claim 6, wherein the locking ring (455) has at least one pin (41) affixed thereto, the at least one pin locking the locking ring in a locking position when the locking ring is biased into a bayonet recess (260, 492) by the elastic device (486).

9. The surgical reamer spindle of claim 8 wherein the drive train (207) is selected from a group of drive trains consisting of nickel titanium drive trains, ferrous metal drive trains, flexible round wound cable drive trains, flat wire wound cable drive trains, gear-driven shaft drive trains, and drive trains having shafts connected via universal joints.

10. A surgical reamer spindle kit (600) including:
a surgical reamer spindle drive train (207) having, at one end thereof, a reamer holder (120); and

Replaced by ART 34 AMDT

at least one matching pair of housing members (313, 314; 413, 414) capable of receiving the drive train and constraining the drive train in an operational orientation.

11. The surgical reamer spindle kit of claim 10 comprising at least two matching pairs of housing members (313, 314; 413, 414) of differing form, each form suitable to suit different surgical protocols.

12. The surgical reamer spindle kit of claim 10 further comprising at least one surgical reamer (1).

13. The surgical reamer spindle kit of claim 10, further comprising a femoral prosthesis (604).

14. . The surgical reamer spindle kit of claim 10, further comprising an acetabular cup prosthesis (606).

15. The surgical reamer spindle kit of claim 10, further comprising an impactor (602).

16. The surgical reamer spindle kit of claim 10 further comprising a sterilization case (610).